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How FDA Warning Letters to Other Companies Increase Your Business' Litigation Risk

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Most food manufacturers today know that receipt of an FDA Warning Letter about a labeling issue creates litigation risk. If the FDA has concerns that a label may be misleading, a consumer class action on the exact same issue is usually not far behind. But recent developments have made the impact of such letters even more far-reaching. Increasingly, FDA Warning Letters are being used to support consumer class actions *against other companies*, and courts have allowed claims based on those letters to move forward toward trial.

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The Ninth Circuit Court of Appeals, which reviews lower court decisions from the infamous "food court" in the Northern District of California, recently issued such a decision. In 2013, a class action lawsuit was filed against Dole Food Co., Inc. for its allegedly deceptive use of the term "all natural" on some of its fruit products' labels. The plaintiff argued that Dole's label stating products were "all natural" was deceptive in that its fruit was actually packaged in citric and ascorbic acid, which are "man-made, mass-produced ingredients."

In support of this contention, the plaintiff noted that the FDA sent warning letters to other companies, questioning descriptions of their products as "all natural" when those products were packaged in "synthetic citric acid." The plaintiff argued that, as the agency charged with regulating the marketing of the nation's food products, the FDA's guidance and warning letters should be viewed as dispositive on the issue. The lower court sided with Dole, finding that its labels were not deceptive or misleading within the meaning of the FDA, based on evidence the parties submitted about the actual products at issue.

The court's refusal to view FDA guidance or warning letters as dispositive was in line with several other lowers courts' decisions in suits over similar misbranding claims. The majority of these courts held that such FDA documents did not constitute "final agency action" because, as stated in the letters themselves, the "FDA's instructions are not final demands, but rather intermediate requests for voluntary compliance." Indeed, each FDA guidance document is prefaced with the disclaimer that it "do[es] not establish legally enforceable responsibilities" and should be viewed "only as [a] recommendation." Moreover, the FDA itself has been clear on its policy that its warning letters, too, are "informal, advisory, and not intended to serve as final agency action," but are rather intended to communicate the agency's position on a matter, without actually forcing it to take enforcement action.

Despite this seemingly clear instruction from the FDA that its guidance and warning letters are not to be interpreted as final agency action, the Ninth Circuit reversed the lower court's decision. The three-judge panel agreed that a jury should hear the plaintiff's argument that Dole's labeling was deceptive, based in large part on the FDA warning letters sent to other companies for similarly labeling a product containing allegedly synthetic citric acid as "natural." The panel concluded that "[t]aken together, this evidence could allow a trier of fact to conclude that Dole's description of its products as 'All Natural Fruit' is misleading to a reasonable consumer." Shortly after this decision, the Ninth Circuit reaffirmed its holding that FDA

guidance and warning letters may be used to create a genuine issue of material fact — in other words, to get a plaintiff to a jury.

In *Bruton v. Gerber Prods.*, the plaintiff claimed that Gerber's baby food products contained claims about nutrient and sugar content that were in violation of FDA regulations. In support of this claim, the only evidence the plaintiff offered beyond his own testimony about being misled by Gerber's labels and the labels themselves were two FDA warning letters. From this evidence alone, the Ninth Circuit held that a reasonable jury could conclude that Gerber's labels were likely to deceive members of the public. In doing so, the Ninth Circuit reaffirmed its position: that FDA guidance and warning letters may serve as evidence sufficient to create a genuine issue of material fact, whether sent to the defendant itself or to a similarly situated manufacturer.

What This Means for Food Manufacturers Going Forward

The influx of litigation against food manufacturers for alleged deceptive or misleading labeling is not new. But the Ninth Circuit's holdings in *Dole* and *Bruton* have raised the stakes by making it harder to dispose of the claims before trial. Apparently, not only are FDA documents — specifically warning letters — enough to get a plaintiff to a jury, but the documents need not even be addressed to a particular company for them to be used against that company.

The potential effect of *Dole* and *Bruton* is twofold: first, whereas receiving an FDA warning letter used to only mean that the FDA was "request[ing] voluntary compliance," it now means that the recipient is an easy target for being hit with a class action lawsuit, and that the class action may drag on and barrel toward trial.

FDA warning letters are published on the agency's website as soon as they are sent to a particular company, meaning that a plaintiff's attorney need only peruse the website to find a plaintiff who purchased a similar product from any other company before filing a class action. For instance, under *Dole*, if a manufacturer labels something as "all natural" that allegedly contains synthetic citric acid, a warning letter sent to a different manufacturer on a similar issue can be used against it at trial. The ease with which these class actions can arise is particularly troubling considering that in 2017 alone, the FDA has published over 150 warning letters on its website.

So, even if a manufacturer does not receive a warning letter itself, it may *still* be susceptible to a class action lawsuit based on warning letters received by other companies. In light of this, manufacturers must stay abreast not only of their own potential regulatory violations, but also of the violations, and potential violations, of other manufacturers to protect themselves against class action lawsuits. In addition, comparing label claims the company is considering to those that are addressed in FDA Warning Letters directed to competitors can ultimately help stay one step ahead of avoiding litigation risk.

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